APR 2 0 2001

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010314

Submitter's Name: George M. Plummer
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Date of Preparation: 1/31/01

Device Name: Dimension® CTNI Calibrator

Classification Name: Calibrator, secondary

Predicate Device: Stratus® CS Troponin I Calibrator (K983722)

Device Description: The Dimension® CTNI Calibrator is a five level frozen product with target concentrations of 0, 2, 10, 25, and 45 ng/mL containing native human Troponin-I complex in a human serum matrix. The kit consists of five vials with two vials at each level.

Intended Use: The CTNI Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Cardiac Troponin-I (Cat. No. RF421C) method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module. This product was designed to meet the needs of users to assure accurate results over the assay range of this method.

Comparison to Predicate Device:

	Dimension® CTNI Calibrator (Modified)	Stratus® CS Troponin I Calibrator
Intended Use	Calibrator	Calibrator
Analyte	Native human Troponin-I complex	Native human Troponin-I complex
Matrix	Human serum	Buffered bovine protein
Form	Frozen	Frozen
Values	Assigned	Assigned
Levels	5 levels	1 levels
Packaging Configuration	2.0 mL vials	Single use cartridge

Comments on Substantial Equivalence: The modified Dimension® CTNI Calibrator is equivalent to the Stratus® CS Troponin I Calibrator. Both products contain native human Troponin-I complex as the analyte source. Both products are intended to be used as calibrators for the troponin-I method.

Conclusion: The modified Dimension® CTNI Calibrator is substantially equivalent to the Stratus® CS Troponin I Calibrator based on the comparison summarized above.

George M. Plummer
Quality Assurance and
Compliance Manager
Date: 1/31/01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 0 2001

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: 510(k) NUMBER: K010314
Trade/Device Name: Dimension® CTNI Calibrator
Regulation Number: 862.1150
Regulatory Class: II
Product Code: JIT
Dated: April 2, 2001
Received: April 5, 2001

Dear Mr. Vaught:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

K010314

Device Name: Dimension® CTNI Calibrator

Indications for Use:
The CTNI Calibrator is intended to be used to calibrate the Cardiac Troponin-I method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module.

George M. Plummer
Quality Assurance and
Compliance Manager
January 31, 2001

(Division Sign-Off)
Division of Clinical Laborator
510(k) Number K010314

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CRF 801.109)

(Optional Format 1-2-96)